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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,294	11/17/2000	Narendra S. Yadav	CL1127 US CIP1	5868

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EXAMINER

MEHTA, ASHWIN D

ART UNIT PAPER NUMBER

1638

DATE MAILED: 10/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b> 09/715,294	<b>Applicant(s)</b> YADAV, NARENDRA S.	
	<b>Examiner</b> Ashwin Mehta	<b>Art Unit</b> 1638	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 05 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed <sup>claim</sup> amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed <sup>claim</sup> amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 39-43, 70, 80-86.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☒ Other: See Continuation Sheet

  
**ASHWIN D. MEHTA, PH.D.**  
**PATENT EXAMINER**

Continuation of 2. NOTE: In claims 82, 84, and 86: it is not clear what promoters are defined as "floral germline promoters." While the specification provides a definition for "floral common germline promoter" and "floral-specific promoter," it is not clear how such promoters differ from floral germline promoters. Applicant provides the example of the AP3 promoter as a floral germline promoter (response, paragraph bridging pages 12-13). However, the specification on page 48 teaches that the AP3 promoter is leaky and apparently serves as a vegetative promoter in some transgenic plant lines. Also, in claims 82, 84, and 86, the recitation, "P3 is a third non-floral somatic tissue or germline promoter" is indefinite. It is not clear if the P3 promoter can be floral germline promoter.

Continuation of 3. Applicant's reply has overcome the following rejection(s): the objection to claim 39 and the rejection of claims 42 and 43 under 35 U.S.C. 112, 2nd paragraph.

Continuation of 5. does NOT place the application in condition for allowance because: the claim amendments and/or Applicant's arguments do not overcome the rejection of claims 82, 84, and 86 under 35 U.S.C. 112, 1st paragraph. Applicant argues that the claims have been amended to include the limitation that P2 is a floral germline promoter, and P3 is a non-floral somatic tissue or germline promoter. However, it is not clear that the use of these promoters would prevent the expression of the transgene operably linked to P3 in the first generation plant. Applicant cites AP3 as an example of a floral germline promoter. However, the specification also admits that this promoter is leaky and can act as a vegetative promoter (page 48). Further, the amended claims still indicate that P3 can be a germline promoter. The claimed methods still then allow for the removal of the STP in the third recombinase element, and operable linkage of P3 with TG followed by TG expression, in the first generation plant.

Applicant's response also does not overcome the rejection of claims 39-41, 70, and 80-86 under 35 U.S.C. 103(a). Applicants argue that the level of predictability for the functioning of multiple SSR systems simultaneously in plants is low, and that one could not have predicted that combinations of these systems would work. Applicants argue that it is well known in the art that expression of certain recombinases is toxic to some tissues, and cite two journal articles (Hiedmann et al. and Silver et al.), which were published after the filing of the instant application, as support (response, page 13, last full paragraph). However, the articles cited by Applicants discuss the effects of Cre recombinase expression on *Drosophila* and mammalian cells, not plant cells. Applicants state that expression of multiple SSR systems in plants has not been demonstrated prior to their invention (response, page 13, last full paragraph). However, it is also noted that the instant specification does not demonstrate that the simultaneous expression of two or more site-specific recombinase systems in plants. Applicants also argue, that the prior art does not suggest the combination of promoters required for claims 81-86 (response, page 14, 1<sup>st</sup> full paragraph). The Examiner maintains that it does, for the reasons stated in the previous Office actions. It is also noted that amended claims 42 and 43 would again be included in this rejection. The rejection was withdrawn from these claims in the previous Office action only because they had become dependent on cancelled claims.

Continuation of 10. Other: The amendment to page 1 of the specification, correcting the claim to priority, has been entered. .